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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,799	06/18/2007	Tetsuya Yagi	P30115	6997

7055 7590 01/14/2011
GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1657

NOTIFICATION DATE	DELIVERY MODE
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01/14/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/582,799	YAGI ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/16/11.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/10/10, 8/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group I, claims 1-9, in the reply filed on 12/16/10 is acknowledged. Please update the continuing information in the preamble of the specification.

The present claims are drawn to class C beta lactamase with no specificity. The naming of beta lactamases is a bit complicated where there are Groups 1-4 as well as independently Groups A-D. Class C is better known as AmpC which is under Group 1. And under Class C there are a number of subtypes under CMY classes. A reading of the specification reveals the point of novelty may reside in employing Kirby Bauer type disks to apply reagents to bacterial specimens to determine class C beta lactamase producing bacteria.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Shoichet in view of each of Black and Arakawa.

Shoichet (6,448,238) entitled "Inhibitors of beta Lactamases and Uses Therefor" teaches in column 3 first paragraph m-aminophenylboronate is a lactamase inhibitor. In column 24 last paragraph boronic acid inhibitors were tested over a range of concentrations with various ratios of ceftazidime with controls. In the following tables results of different inhibitors with different lactamases are shown including AmpC lactamase.

The claims differ from Shoichet in that they specify the reagents are applied to the bacteria with disks containing an antibiotic and a lactamase inhibitor.

Black (WO 03/078654) entitled "Device and Method for Detecting Antibiotic Inactivating Enzymes" teaches on page 5 last paragraph bridging to page 6, double disk potential test where disks containing lactamase inhibitors are placed at some distance from antibiotics to determine if the bacteria produce a specific type of lactamase which would be susceptible to that type of inhibitor. See example 5 on pages 20-21. On page 22 first paragraph a AmpC disk test is described with cefoxitin.

Arakawa (J of Clinical Microbiology) entitled "Convenient Test for Screening Metallo Beta Lactamase Producing Gram Negative Bacteria by Using Thiol Compounds" teaches on page 40 column 2 last paragraph bridging to next column, contacting a colony of different bacteria" strains with Kirby Bauer disks containing a beta lactam drug and with different beta lactamase inhibitors.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the method of Shoichet with disks as taught by Black and Arakawa because disks have more standardization and convenience in a commercial lab as compared to the various solutions made up in a research lab as performed by Shoichet. The specificity of class C beta lactamase would have been obvious because inhibitors specific to that type of lactamase are known for the same function as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 line 3 and all occurrences, "at an interval" is not understood, is it an interval of time, space, location? In claim 1 lines 5-6, "the inhibitory zone" lacks antecedent basis. Method claim 1 is incomplete where it lacks any step such as correlating to accomplish the preamble of the claim. It is noted that the claims are not drawn to any specificity regarding class C beta lactamase and are merely inclusive.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Brun-Buisson (The Lancet) teaches transferable lactamase resistance.

Glinka (2008/0146535) teaches beta lactamase inhibitors.

Freire (2005/0124580) teaches beta lactamase inhibitors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

Ralph Gitomer
Primary Examiner
Art Unit 1657